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I	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
	10/603,279	06/25/2003	Lee Michael Teras	9286	4437
	7590 01/17/2007 THE PROCTER & GAMBLE COMPANY INTELLECTUAL PROPERTY DIVISION WINTON HILL BUSINESS CENTER - BOX 161 6110 CENTER HILL AVENUE CINCINNATI, OH 45224			EXAMINER	
				THAKUR, VIREN A	
				ART UNIT	PAPER NUMBER
				1761	
r					
L	SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/17/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)				
	10/603,279	TERAS ET AL.				
Office Action Summary	Examiner	Art Unit				
	Viren Thakur	1761				
The MAILING DATE of this communication ap Period for Reply	pears on the cover sheet with the	correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D. - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period. - Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be to will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDON	N. mely filed nthe mailing date of this communication. ED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 31 (esponsive to communication(s) filed on <u>31 October 2006</u> .					
2a)⊠ This action is FINAL . 2b)☐ Thi	s action is non-final.					
·— · · ·	☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims	·					
4) Claim(s) 1-5,8-15 and 41-44 is/are pending in	4) Claim(s) 1-5,8-15 and 41-44 is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.	6)⊠ Claim(s) <u>1-5,8-15 and 41-44</u> is/are rejected.					
7) Claim(s) is/are objected to	or election requirement					
8) Claim(s) are subject to restriction and/	or election requirement.					
Application Papers		·				
9)☐ The specification is objected to by the Examin						
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
	xammer. Note the attached Ome	C Addition of tolling 1 to 102.				
Priority under 35 U.S.C. § 119	·					
	12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
, ,	a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received.					
 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage 						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
•						
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summa					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)	Paper No(s)/Mail 5) Notice of Informal					
Paper No(s)/Mail Date	6) Other:					

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DETAILED ACTION

Response to Amendment

- 1. As a result of the amendment to the claims the rejection under 35 U.S.C. 112, first paragraph of claims 1-5, 8-9, 11-15, 21-25 and 41-44 has been withdrawn.
- 2. As a result of the amendment to the claims the rejection under 35 U.S.C. 112, second paragraph of claims 1-5, 8-10, 11-15, 21-25 and 41-44 has been withdrawn.

Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 4. Claim 10 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons cited in the prior Office Action, mailed May 31, 2006. The method claim 10, still recites the phrase "reducing the level of acrylamide." As previously cited, this actual method step

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would be impossible for one skilled in the art to carry out, for in order to perform the claimed method, the corn-based food product must have an initial amount of acylamide. However, the (natural) starting corn-based food composition does not possess acrylamide prior to heating. Therefore, addition of an asparagine-reducing enzyme could not result in any reduction of acrylamide in the corn-based food product, as presently recited. Since acrylamide is not present in a food product prior to heating, there is no baseline from which acrylamide is reduced. Thus, the claim fails to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

5. Claims 1-5, 8-15 and 41-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to the above specified claims recite the limitation "asparagine is converted to a different substance or removed." The limitations thus state that the asparagine can be removed or alternatively converted into *any* substance that is not asparagine. Support for this amendment was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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- 6. Claims 1-5, 8-15 and 41-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing asparagine, does not reasonably provide enablement for converting asparagine to a different substance. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claim limitations indicate that asparagine can be converted to *any* substance. The specification does not provide support for and thus does not enable one having ordinary skill in the art to convert asparagine to a different substance.
- 7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 8. Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim is directed to an article of commerce. Therefore, the amendment including the step of heating the cornbased food product does not correspond with the preamble. The amendment is directed to a method step while the claim is directed to a product. Appropriate correction is required.

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Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 11. Claims 1-5, 8-15 and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elder et al. (US 20040058054). The reference and rejection are incorporated as cited in the previous Office Action, mailed May 31, 2006.

Response to Arguments

12. Applicant's arguments filed October 31, 2006 have been fully considered but they are not persuasive in light of the previously stated reasons of record. Applicant

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asserts that the cited reference to Elder '054 not only does not teach or suggest Applicants' invention but also fails to provide a reasonable expectation of success between its examples, particular example no. 5, and the claimed subject matter of Elder '054, namely reducing the presence of acrylamide in thermally processed food. Thus, Applicant states, that Elder '054 failed to appreciate the difficulty in adding or applying an asparagine-reducing enzyme to corn-based food material. Applicant further notes that there are stark differences between Applicants' corn-based food material and Elder's simple sugar and amino acid filled test tube.

Regarding this assertion, the Examiner respectfully disagrees. Elder et al. recognized that a result of heating carbohydrate foods is the formation of acrylamide (paragraph 0004) and further asserts that the object of the invention was to prevent the formation of said acrylamide by targeting the reaction through which acrylamide forms (see abstract and paragraph 0005). Paragraph 0004, 0008 and 0011 provide further evidence that Elder et al. recognized the need for incorporating the asparagine inactivating enzyme into the food, such as food products comprising corn. Therefore, Elder et al. have disclosed how acrylamide is formed in the food and a method for reducing the presence of acrylamide in a thermally processed food. Furthermore, regarding example 5, Applicants' assert that glucose is added to asparagines and then heated to form acrylamide and further that Elder et al. never achieve this in food; however, the Examiner asserts as discussed above that Elder et al. have disclosed reducing the presence of

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acrylamide in a thermally processed food. Additionally, in disclosing glucose and asparagine and adding an asparagine-reducing enzyme to the mixture, it is noted that glucose is considered a food and thus Elder et al. indeed disclose using an asparagine-reducing enzyme in food so as to prevent and reduce the formation of acrylamide when heating.

Regarding establishing a *prima facie* case of obviousness, it is noted that no substantial modification of the reference is necessary. No secondary reference teaching is required to modify the primary reference and meet the claim limitations. The rejection was made under 35 U.S.C. 103(a) because, while the reference did not specifically describe actually carrying out the method steps necessary to produce the food product as instantly claimed, it does provide the necessary teachings in order to carry out such methods described therein. In other words, the references teaches how to carry out the invention; it simply did not provide examples for each and every possible method and resultant food product or article, and as such, the rejection was made under 35 U.S.C. 103(a) such that it would have been obvious to follow these teachings and suggestions to carry out the invention disclosed therein.

Applicants further assert that Applicants' disclosure appreciates the difficulty in adding or applying an asparagine-reducing enzyme to a corn-based food product while Elder '045 failed in this appreciation. The Examiner further disagrees for the reasons cited in the previous Office Actions, mailed May 31, 2006, on pages 6 and 7, and February 24, 2005, on page 5. If the addition of an

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enzyme to a composition involves complex maneuvers and is such a difficult task, then Applicant's claims should reflect this. Furthermore, the specification of the Applicant generally describes the addition of enzymes whereby "the enzyme may be added to the corn-based food material in any suitable manner, such as directly (for example, sprinkled, poured or sprayed on the corn-based food material, or the corn-based food material can be soaked in an enzyme solution) or indirectly." This is not deemed persuasive for the reasons of record. It is not agreed that the addition of the enzyme by sprinkling, pouring or spraying on the food material, or soaking the food material in an enzyme solution would constitute a greater appreciation of adding said enzyme to said corn-based food material. It is not agreed that the addition by the above stated means is a much more robust and definitive disclosure.

As Applicant correctly states, *prima facie* case of obviousness requires some suggestion or motivation, either in the references themselves or *in knowledge generally available to one of ordinary skill in the art* to modify the reference or combine the reference teachings. In light of this, one of ordinary skill in the art would readily know how to add the enzyme to the food material, as the very nature of the use of isolated enzyme compositions over the past several decades necessarily involves these or other rudimentary application techniques. This knowledge in combination with the Elder et al.'s teachings provides the motivation that it would have been obvious to incorporate an asparagine-reducing enzyme, through a means known to one having ordinary skill in the art,

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for the purpose of reducing the reaction yield of acrylamide. Furthermore, the invention of Elder et al. aims to reduce the formation of acrylamide *in foods* by targeting the reaction that produces this compound. Therefore, it would have been obvious to one having ordinary skill in the art that said asparagine-reducing enzyme must be incorporated into the food in order to reduce the acrylamide formed when heating the food. Furthermore, in paragraph 0011 Elder et al. provide evidence of one such method of adding the asparagine-reducing enzyme. As previously stated, other methods for the incorporation of an enzyme into a food product have been well known by one having ordinary skill in the art.

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Regarding claims 41-44, Applicants' assert that Elder '054 or knowledge of one having ordinary skill in the art would not teach or suggest Applicants' invention. As stated, Applicants assert that nothing in Elder '054 teaches or suggest an article of commerce that communicates the reduction or lowness of acrylamide in Applicants' corn-based food material, or any other kind of food. The Examiner respectfully disagrees. For the reasons of record and for the reasons discussed above, Elder et al. disclose an asparagine-reducing enzyme in a food product (Paragraph 0004, 0008, 0011 and Page 3, Column 1). Elder et al. further disclose manufacturing potato chips from raw potato slices (Paragraph 0008). One having ordinary skill in the art recognizes that in manufacturing a food product, that said food product would have been packaged in some form of a container. Manufacturing of a food commonly involves packaging of the food. However, providing a label on said container with a message that said food

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product has reduced levels of acrylamide is not a special technical feature to the invention – which is a method for reducing the formation of acrylamide. Additionally, as stated on page 7 of the previous Office Action, mailed May 31, 2006 and page 7 of the previous Office Action, mailed February 24, 2005, the particular message regardless of how it is placed on the container would not provide a patentable feature to the invention. The printed matter on the label of the instantly claimed container is not integral to the function of the claimed article, for example, as opposed to a situation where the printed matter serves as an indicator for measurement, thus affecting the use and function of the article as a whole. Therefore, a simple message which could further aid the marketing and promotional potential of said container would not alter or change the tangible, material functions of the article, namely those involving the corn-based food product and the container. Additionally, such a message stating that the product has a reduced level of acrylamide would not patentably differ from the same article with any number of differing messages. Therefore, such a label is not a patentable feature over the prior art.

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Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application

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claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 41-44 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-12 of copending Application No. 10/606137.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 1-5, 7-44 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 and 42-50 of copending Application No. 10/606137.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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16. Claims 11-44 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/603978.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's comments filed October 31, 2006 have been fully considered but they are not persuasive. Applicant's comments reflect those presented previously, and the rejections are maintained for the reasons of record.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Viren Thakur whose telephone number is (571)-272-6694. The examiner can normally be reached on Monday through Friday from 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571)272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pairdirect.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (tollfree). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Viren Thakur Examiner

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PRIMARY EXAMINER